

A simple model of reverse settlements in pharmaceutical markets with authorized generics

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Abstract

We present a simple model of strategic interaction between an incumbent pharmaceutical firm and a potential entrant. In the US pharmaceutical market potential entrants and incumbent will enter often times into so-called reverse settlements, in which the incumbent will make payments to the generic firm in exchange for the generic firm's agreement to delay entry into the market.

We are interested in the incumbent's incentive to make a reverse settlement offer to the entrant and his incentive to launch an authorized generic, should there be no settlement. Additionally, we study the welfare outcomes for consumers under different scenarios and consider whether and how a policy-maker can influence the two firms' decisions through the use of subsidies and taxes, and the use of restrictions on authorized generics.

We demonstrate that a policy-maker can prevent a reverse settlement from occurring by subsidizing the incumbent for launching an authorized

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generic. We demonstrate that there can be instances in which such subsidies can be welfare-enhancing: Not only do consumers obtain more surplus, but the gain in consumer surplus exceeds the cost of subsidies.

We also find that a ban on guarantees by the incumbent not to launch an authorized generic weakly benefits consumers. In contrast, a ban on authorized generics only sometimes benefits consumers.

1 Introduction and literature

In 1984 the U.S. Congress passed the Drug Price Competition and Patent Term Restoration Act, commonly known as the Hatch-Waxman Act. The Hatch-Waxman Act created a streamlined mechanism under which, among other things, generic manufacturers could submit a so-called Paragraph IV Abbreviated New Drug Application (ANDA) challenging an existing patent in order to gain entry into a patent-protected product market. Given the high financial stakes involved in these markets¹, Paragraph IV ANDAs have been subject to intense litigation and negotiations, often times leading to so-called reverse settlements in which the incumbent patent-holding manufacturer would make payments to the generic firm in exchange for the generic firm's agreement to delay entry into the market. These reverse settlements have been and continue to be controversial, with court decisions being divided on their legality². Furthermore, reverse settlements have evolved over time from simple "payment-

¹According to the FTC (2010), by the end of the fiscal year of 2008, patent-protected drugs facing Paragraph IV ANDA challenges had an estimated annual aggregate sales volume of \$90 billion.

²In the 2003 Cardizem CD case the Court of Appeals for the 6th Circuit found that reverse settlements were to be considered per-se illegal, meaning automatically prohibited regardless of the potential (economic) merits of the settlement. However the same year in the Schering-Plough case, the 11th Circuit held that the legality of settlements was to be judged under the rule-of-reason standard. The rule-of-reason approach to reverse settlements and specifically payments as part of such settlements was affirmed by the 2nd Circuit in the Tamoxifen case of 2005 (see Thomas (2006a) for details).

for-delay" agreements to more complex ones that involve licensing agreements³, and, most importantly promises by the incumbent firm not to launch an competing generic product (also known as an authorized generic) should the generic manufacturer in fact enter the market.

Authorized generics in specific have received much attention by the antitrust authorities as evidenced in FTC (2009) report on authorized generics. Given that the Federal Trade Commission is currently taking an increasingly skeptical view on the legality of "pay-for-delay" agreements as part of reverse settlements (see FTC (2010)), authorized generics and agreements on authorized generics are likely to become an even more important and integral part of future reverse settlements.

In this paper we present a simple model of price competition between two (pharmaceutical) firms which offer differentiated products (brand and generic products), that captures the strategic nature of decision-making in a market with an incumbent firm and a potential entrant. We are interested in particular in the incumbent's ability to make a reverse settlement offer to the entrant (which entails a payment to the entrant in return for the promise by the entrant not to enter the market or to delay entry into the market) and should there be no settlement, the incumbent's option of launching an authorized generic.

We examine whether authorized generics are beneficial or harmful to consumers. In that vein, we also address what effect possible policy responses such as bans on authorized generics or bans on agreements on authorized generics have on consumer welfare. Finally, being interested in the welfare outcomes for consumer under different scenarios, we consider whether and how a policy-maker can influence the two firms' decisions through the use of subsidies and taxes in order to improve consumer welfare.

We show that absent any intervention by the policy-maker the incumbent firm will offer a reverse settlement, if monopoly profits exceed the aggregate

³see Hemphill (2007) and Hemphill (2009) for accounts of the evolution of reverse settlements, especially in light of the changing legal environment.

profit under competition. The (potential) entrant will accept as long as the offer is at least as high as the amount of profit he could obtain under competition.

We further argue that a policy-maker can prevent a reverse settlement from occurring by subsidizing the incumbent for launching an authorized generic. In a numerical example we demonstrate that there are instances in which such subsidies are welfare-enhancing: Not only do consumers obtain more surplus, but the gain in consumer surplus exceeds the cost of subsidies.

Reverse settlements (within the context of the Hatch-Waxman Act) have been studied by a number of legal scholars as well as economists:

Hylton and Cho (2010) distinguish conditions under which two parties may agree to a reverse settlement as opposed to a standard settlements (which in this the Hatch-Waxman context would involve a generic paying the incumbent for not blocking entry). They show that in the presence of litigation costs a settlement will be observed if it is "cheaper" to settle than to litigate (or if the gains from avoiding litigation (and thus maintaining the status quo) are higher than the net cost of maintaining the status quo then settle for standard settlements, and, if gains from avoiding litigation (and thus reverting to a monopoly) are higher than the net cost of reverting to monopoly). The paper does not discuss the role authorized generics (or agreements related to authorized generics) in reverse settlements.

Lave (2002) provides a stylized model that describes the trade-offs faced by the incumbent and generic entrant. He shows that the incumbent's and generic's decision to develop a drug will depend on future expected profits. These in turn are influenced, by the size and likelihood of a reverse settlement in the future. The paper's primary focus of attention is on the economic effects of allowing or banning particular clauses, that foreclose entry into the market, from being part of reverse settlements.

Bulow (2003) discusses how firms "game the law", that is, how they strategically exploit the provisions of Hatch-Waxman to their advantage while causing competitive harm/harm consumers. While the role of authorized generics is

mentioned and some policy recommendations are offered, his focus is on the most primary parameters of reverse settlements (side payments, the extent of delay in entry) and how some provisions of the Hatch-Waxman law allow firms to strategically create "bottle-necks" in terms of market entry.⁴

In addition, several papers have addressed the role of and issues surrounding authorized generics in reverse settlements/authorized generics as an exclusionary device:

The Federal Trade Commission (2009) provides a descriptive survey of reverse settlements between 2004 and 2008, detailing the use of authorized generics in those settlements. Additionally, their survey provides data on the impact of generic entry/authorized generic entry on market prices.

Both Chen (2007) and Devlin (2007) provide discussions of authorized generics from an antitrust perspective: Describing the peculiar characteristics of pharmaceutical markets, Chen (2007) emphasizes how authorized generics will likely deter generic entry and negatively impact competition in those markets. Suggestions for remedies include various mechanisms which would curtail an incumbent firm's ability to launch an authorized generic, especially with regard to the timing of such a launch. Being a legal treatment of the issue, the paper does not provide any formal economic analysis.

Devlin (2007), similar to Chen, focuses on the legal aspects surrounding authorized generics in his analysis. In contrast to Chen he provides for a sympathetic view of authorized generics by contrasting concrete short-run benefits from authorized generics in reducing market prices against more - in his view - vague claims of future competitive harm. What his paper does not address is how or whether the mere possibility of a launch of an authorized generic would influence generic entry and their willingness to agree to a reverse settlement.

Berndt et al. (2007) argue that their data on prices and market shares

⁴Note that in 2003 the original Hatch-Waxman Act was slightly modified by the Medicare Prescription Drug, Improvement and Modernization Act of 2003, which partially addressed issues raised by Bulow (2003). See Hemphill (2009) for details.

for generic drugs in the years 1999-2003 is consistent with the assertion that authorized generics on balance benefit consumers. However, the analysis is limited among other things that it does not account for differences in market characteristics for different drugs, it relies on a fairly small data set and provides no theoretical rationale for their findings.

Reiffen and Ward (2005) present a model of (branded) generic entry, where the incumbent firm can raise prices and its own profits by introducing an authorized generic. The model result is based on the idea that in the presence of fixed costs to entry, the presence of an authorized generic would discourage entry by some firms, especially if the market is small and if there already are several firms present in the market. The focus of the paper is on the long-run equilibrium of the market, when entry to the market is unrestricted. In contrast, this paper focuses on the initial period where the stipulations of the Hatch-Waxman act limit the market to at most two firms.

The remainder of the paper is organized as follows: Section 2 drawing heavily on Thomas (2006b), Chen (2007) and Bulow (2003) gives an overview of provisions of the Hatch-Waxman act with regard to a generic manufacturer attempting to enter a patent-protected market. Section 3 provides a reduced-form model of the strategic interaction between incumbent and the potential generic entrant and also addresses the question of how the policy-maker may influence the market outcome through lump-sum transfers. Extending this model in section 4, we explicitly model the price-setting decisions made by each firm and provide conditions under which a threat by the incumbent to release an authorized generic is credible. We further provide an example of how the policy-maker can set per-unit taxes and subsidies such that it achieves a (consumer-)welfare improving outcome. Finally, section 5 summarizes the findings and provides concluding comments.

2 Institutional details: The Hatch-Waxman act

Under the Hatch-Waxman Act generic manufacturers can apply for drug approval (and thus entry into a patent-protected pharmaceutical market) under one of the following four possible "certifications" for each patent that is referenced by the incumbent drug: (1) the required patent information has not been filed, (2) the patent has already expired, (3) ANDA approval is sought after the patent expires and (4) the patent is invalid or will not be infringed upon by the ANDA.

The most contested of these certification is the last one listed, also known as a "Paragraph IV" certification. This is because under a ANDA Paragraph IV certification a generic manufacturer is attempting to enter a market prior to the expiration of the patent while under all other certifications the market at the time of entry would no longer be patent-protected.

Given the litigation-prone nature of a Paragraph IV ANDA, the Hatch-Waxman act provides for an automatic stay of any approval of the ANDA if the incumbent (as the patent holder) files a patent infringement suit within 45 days of the ANDA. The stay will have a duration of up to 30 months unless the patent expires within that period or court decision determines that the patent was not infringed upon.

Additionally, the act awards the first company to file a Paragraph IV ANDA a "180 day exclusivity right". Once an ANDA filer receives the exclusivity right, no other ANDA may be approved for the same drug for at least 180 days after the first filer starts to market its product, or a court decisions has declared the patent invalid or not infringed upon, whichever event comes sooner. Given that the 180 day exclusivity right is only triggered under either of those two conditions, it is possible for the incumbent firm to block all entry to the market if he can reach a settlement with the first filer (within the first 45 day period) wherein the first filer agrees to not enter the market and ultimately no infringement suit is filed. In fact, such outcomes have been observed in numerous ANDA cases which then creates a "bottle-neck" as described.(Subsequently the rules

on the 180 day exclusivity right were modified in the Medicare Modernization Act of 2003, but even under the new rules firms can still deliberately create a "bottle-neck" (see for Hemphill (2009), p. 20 for details.)

The availability of a "180 day exclusivity" period is important for two reasons: First, it limits competition initially to a two-firm setting, during which the entrant is able to obtain substantial profits. Because this exclusivity is valuable to the entrant many reverse settlements will specifically preserving the exclusivity period for the entrant (by avoiding the triggers mentioned above). Second, because the incumbent firm is not subject to the 180 day exclusivity provisions, it may introduce an authorized generic during that period which of course would significantly diminish the profits obtained the first-filer entrant. Thus, guarantees made by the incumbent from refraining to introduce an authorized generic are valuable for the entrant firm, if it can retain exclusivity.

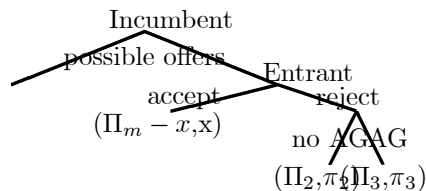
3 Basic Model

Considering the situation following the filing of a Paragraph IV ANDA, we can describe it by the following dynamic game with complete information between an incumbent firm and a first-filer (generic) entrant: Faced with a potential generic entrant, the incumbent decides whether to make a reverse settlement offer to the entrant. For simplicity we will assume that the offer consists of a payment x made to the entrant and potentially the guarantee that the incumbent will refrain from launching an authorized generic, should the entrant defer his entry into the market. Given the offer x , the entrant decides whether to accept or not. If he accepts then the brand maintains a monopoly in the market and sets the price for his product. Should the entrant reject the offer x then the entrant decides whether or not to enter the market. Upon observation of the entrant's decision the incumbent decides whether or not to launch an authorized generic (in addition to continuing to produce the branded product). We will initially assume that both firms will produce and sell their product (if at all) during a

single period. We will then extend the model to a setting where there are two periods and where the entrant will defer entry for at most the first period. This allows us to capture situations in which an entrant may delay entry and benefit from a reverse settlement in which the incumbent guarantees not to launch an authorized generic.

We will denote the possible payoffs in such a game as follows: If the incumbent is a monopolist his profit (in any given period) is Π_m , while in a situation where the incumbent competes against the entrant his profit in any period is given by Π_2 and Π_3 respectively, depending on whether he does not or does offer an authorized generic. The entrant's profits in such circumstances is given by π_2 and π_3 respectively.

The graph below depicts the game as an extensive form game:



3.1 Basic results

We will examine the game by backwards induction:

Suppose the entrant had rejected the offer made the incumbent. Then the incumbent will have to decide whether or not to launch an authorized generic. If $\Pi_3 > \Pi_2$ then it would be in his interest to do so, otherwise he will prefer to only offer the brand-name product.

Anticipating how the incumbent will ultimately decide on the authorized generic, now consider the preceding decision by the entrant whether or not to

accept the incumbent's offer. If he accepts the offer his payoff will be x , while if he rejects his payoff will be π_2 if $\Pi_3 < \Pi_2$ or π_3 if $\Pi_3 > \Pi_2$.

Thus:

Lemma 1 *In equilibrium the entrant will accept any reverse settlement offer $x > \pi_2$ if $\Pi_3 < \Pi_2$ and any offer $x > \pi_3$ if $\Pi_2 < \Pi_3$ and reject them otherwise.*

These calculations now all inform whether and which kind of offer a profit-maximizing incumbent will propose to the entrant. The incumbent will make an offer if the monopoly profit Π_m exceeds the combined profits of the incumbent and entrant should they compete against each other. More formally,

Lemma 2 *If $\Pi_3 < \Pi_2$ then the incumbent makes an offer $x = \pi_2$ as long as $\Pi_m > \Pi_2 + \pi_2$, while if $\Pi_3 > \Pi_2$ he makes an offer $x = \pi_3$ as long as $\Pi_m > \Pi_3 + \pi_3$*

In other words, if it is profitable to collude the firms will do so and in this settings the gains from doing so $\Pi_m - \Pi_2 - \pi_2$ will go to the incumbent (as he holds all bargaining power by virtue of his ability to make a take-it-or-leave-it offer).

3.1.1 Two-period setting

Now we allow two time periods, where any monopoly only can be maintained in the 1st period - as previously mentioned, this allows us to capture situations in which an entrant may delay entry and benefit from a reverse settlement in which the incumbent guarantees not to launch an authorized generic. For simplicity, we will assume that there is no discounting of profits. Settlement offers may now include contractual guarantees by the incumbent to refrain from launching an authorized generic in either period.

Consider now the 2nd period: If the incumbent prefers never to launch an authorized generic, or if both sides prefer a market with an authorized generic, then contractual guarantees do not play a role (either because authorized generics will never be launched or because neither side desires such guarantees). However if the incumbent benefits from launching an authorized generic ($\Pi_3 > \Pi_2$), while the entrant prefers a market without an authorized generic ($\pi_2 > \pi_3$), then there may be scope of a contractual agreement:

Lemma 3 *If $\pi_2 - \pi_3 > \Pi_3 - \Pi_2 > 0$ then the incumbent will offer - as part of a reverse settlement - a contractual guarantee not to launch an authorized generic, combined with a lower compensation to the entrant .*

If the benefits to the entrant are larger than the losses to the incumbent from preventing the launch of an authorized generic, such that $\pi_2 - \pi_3 > \Pi_3 - \Pi_2$, then the incumbent will offer a contractual guarantee in return for a lower settlement payment, since he knows that the value of the contractual guarantee to the entrant is $\pi_2 - \pi_3$.

Under such a settlement the incumbent thus subtracts $\pi_2 - \pi_3$ from the compensation offered to the entrant and will pay the entrant only $x = 2\pi_3 - \pi_2$. In turn, the incumbent achieves a net profits in the 2nd period period: $\Pi_2 - (2\pi_3 - \pi_2)$ rather than a 2nd period payoff of $\Pi_3 - \pi_3$ absent the contractual guarantee. This is, because $\pi_2 - \pi_3 > \Pi_3 - \Pi_2$ if and only if $\Pi_2 - (2\pi_3 - \pi_2) > \Pi_3 - \pi_3$.

3.2 Basic Policy implications

3.2.1 Subsidies to ensure the introduction of an authorized generic

Suppose that within the model described above, we introduce a policy maker who is interested in encouraging the introduction of an authorized generic by way

of subsidies. The question then is how would he have to set subsidies in order to achieve the desired outcome? Let S be the subsidy paid to the incumbent and s the subsidy to the entrant. For the subsidies to induce both firms to compete with one another and for the incumbent to introduce an authorized generic, S and s need to satisfy the following conditions:

For any settlement to be unattractive to the two sides:

$$\Pi_m < \Pi_3 + S + \pi_3 + s \quad (1)$$

Additionally, in order for the incumbent to launch an authorized generic, it is necessary that:

$$\Pi_2 < \Pi_3 + S$$

Rearranging the two inequalities we find that:

Lemma 4 *In order to induce competition between incumbent and entrant with the introduction of an authorized generic, subsidies S and s have to be such that $S > \Pi_2 - \Pi_3$ and $S + s > \Pi_m - \Pi_3 - \pi_3$.*

Notice that the policy maker has some leeway in how he allocates subsidies S and s in order to satisfy the two conditions. That is, the total subsidy $S + s$ will need to be at least as large as the gains in producer surplus $\Pi_m - \Pi_3 - \pi_3$ which would otherwise accrue due to collusion, as long as the incumbent is compensated for any loss caused by the introduction of an authorized generic. Note that the subsidy s to the entrant can always be reduced to zero by choosing a sufficiently large S - the intuition here is that in order to achieve the desired outcome the policy maker must primarily ensure that the incumbent will not offer a settlement and that he will launch an authorized generic.

We can extend the analysis to the two period setting, where $\Pi_3 > \Pi_2$, $\pi_2 > \pi_3$ and $\Pi_2 + \pi_2 > \Pi_3 + \pi_3$. Recall that an incumbent may have an incentive to

propose a reverse settlement in which the entrant delays entry into the market until the 2nd period, in return for a payment $x = 2\pi_3 - \pi_2$ and the contractual guarantee that the incumbent will not launch an authorized generic. Formally, this occurs when

$$\Pi_m - x + \Pi_2 > \Pi_3 + \Pi_3$$

Thus, a policy maker who wants to prevent a reverse settlement will have to offer subsidies S' and s' to the incumbent and generic respectively, such that:

$$\Pi_m - (x + s') + \Pi_2 < \Pi_3 + \Pi_3 + S'$$

which given $x = 2\pi_3 - \pi_2$ we can rewrite as:

$$\Pi_m < 2(\Pi_3 + \pi_3) - (\Pi_2 + \pi_2) + S' + s'$$

Because the right-hand side of the above inequality is less than $\Pi_3 + S + \pi_3 + s$ from inequality 1, we find:

Lemma 5 *In a two-period setting with $\Pi_3 > \Pi_2$, $\pi_2 > \pi_3$ and $\Pi_2 + \pi_2 > \Pi_3 + \pi_3$, the required total subsidy $S' + s'$ to prevent a reverse settlement is larger than the total subsidy required in a one-period setting.*

We see that the policy maker will offer larger incentives to prevent a settlement and induce the incumbent to launch an authorized generic because the second period provides an additional opportunity to profit from a settlement.

3.2.2 Ban on guarantees about authorized generics in reverse settlements

The threat to introduce authorized generics have been criticized by the FTC (2009) as discouraging entry and anticompetitive. Thus, it has been advocating curtailing/banning the ability for incumbents to introduce authorized generics and the converse ability to makes guarantees on refraining from launching authorized generics. One indirect way to reduce the impact of the threat is to prohibit contractual guarantees about authorized generics to be part of reverse settlements. Such a ban only will affect situations in which $\Pi_3 > \Pi_2$, $\pi_2 > \pi_3$ and $\Pi_2 + \pi_2 > \Pi_3 + \pi_3$. Under such circumstances, a ban will have two effects: First, in the 2nd period, three products (brand, generic and authorized generic) will be offered irrespective of whether there is a settlement or not. Second, the incumbent cannot rely on the threat to introduce an authorized generic to lower the compensation paid as part of a reverse settlement - thus, for the incumbent will offer a settlement the monopoly profits will have to be higher than absent the ban. The overall effect, from the consumers' point of view, is weakly positive:

Proposition 6 *In a two-period setting with $\Pi_3 > \Pi_2$, $\pi_2 > \pi_3$ and $\Pi_2 + \pi_2 > \Pi_3 + \pi_3$, a ban on contractual guarantees regarding an authorized generic weakly benefits the consumer. If $\Pi_m > 2(\Pi_3 + \pi_3) - (\Pi_2 + \pi_2)$, then the ban increases competition. If $\Pi_m < 2(\Pi_3 + \pi_3) - (\Pi_2 - \pi_2)$, then the ban does not affect the market outcome.*

A ban on contractual guarantees ensures that the number of products available in the second period (sometimes) increases from two to three. At the same time the ban does not make reverse settlements more attractive to the two firms. Thus the ban weakly benefits the consumer.

3.2.3 Ban on authorized generics

Going back to a model with a single period, now consider another policy option - a ban on authorized generics: While such a ban has no impact when $\Pi_2 > \Pi_3$, because under such conditions the incumbent would not be interested in launching an authorized generic regardless, the ban does influence market outcomes when $\Pi_2 < \Pi_3$. We find,

Proposition 7 (i) *If $\Pi_3 > \Pi_2$ and $\Pi_2 + \pi_2 > \Pi_3 + \pi_3$ then a ban on authorized generics prevents reverse settlements if $\Pi_m < \Pi_2 + \pi_2$. For situations where $\Pi_m < \Pi_3 + \pi_3$ a ban hurts consumers by limiting competition to two products.*
(ii) *If $\Pi_3 > \Pi_2$ and $\Pi_2 + \pi_2 < \Pi_3 + \pi_3$ then a ban on authorized generics never prevents reverse settlements and reduces competition.*

Recall, that a reverse settlement occurs when the monopoly profit Π_m exceeds the combined profits under competition. A ban on authorized generics fixes the combined profits under competition to $\Pi_2 + \pi_2$. Thus, if $\Pi_2 + \pi_2 < \Pi_3 + \pi_3$ the ban worsens the attractiveness of competition. If $\Pi_2 + \pi_2 > \Pi_3 + \pi_3$, then the ban raises the attractiveness of competition, but this comes at the "price" of limiting competition to two products.

If we were to consider a ban on authorized generics in the two-period setting, we find that the results from the single period setting carry over - for the same reasons as before a ban has no impact when $\Pi_2 > \Pi_3$. When the incumbent does prefer to launch an authorized generic such that $\Pi_2 < \Pi_3$, we find,

Corollary 8 (i) *If $\Pi_3 > \Pi_2$ and $\Pi_2 + \pi_2 > \Pi_3 + \pi_3$ then a ban on authorized generics prevents reverse settlements if $\Pi_m < \Pi_2 + \pi_2$. When $\Pi_m < 2(\Pi_3 + \pi_3) - (\Pi_2 + \pi_2)$ a ban hurts consumers by limiting competition to two products.*
(ii) *If $\Pi_3 > \Pi_2$ and $\Pi_2 + \pi_2 < \Pi_3 + \pi_3$ then a ban on authorized generics always reduces competition.*

In summary, we have shown that policy-maker can achieve a "first-best" outcome for consumers by appropriately subsidizing the incumbent and entrant in order to prevent reverse settlements and ensure the availability of as many products as possible. Whether such subsidization is in fact efficient will be addressed in the subsequent sections.

Absent direct subsidies, the policy-maker may influence the market out either by banning contractual guarantees on authorized generics, or by banning authorized generics themselves. We find that banning contractual guarantees on authorized generics never hurt consumers and interestingly, banning authorized generics in fact sometimes also may benefit consumers.

4 Modelling competition

So far the model neither explicitly modelled the market in which the firms would operate, nor did it describe the mode of competition between the firms. We will now extend the model in both aspects, which will allow us to address social welfare issues and make more detailed predictions about equilibrium outcomes.

We will assume a Hotelling-style game of price competition, where an infinite number of consumers with a total mass of 1 are uniformly distributed along a unit-length line. Each consumer is assumed to have unit-demand and derive utility

$$U(p, b, b') = a - p - (b - b')^2$$

from the consumption of the good, where $a > 0$ is a constant, p is the price of the good, $b \in [0, 1]$ represents the location of the consumer on the unit-length line and $b' \in [0, 1]$ the location of the firm selling the good. We will further assume that the consumer makes a utility maximizing choice where if he declines to buy the good his utility is $U = 0$.

As for the firms we assume that both firms simultaneously set prices for the brand-name product, the authorized generic (if applicable) and the generic

product. We will refer to their prices as p_B , p_{AG} and p_G respectively. For the incumbent the per-unit production cost is given by c_B and for the entrant by c_G . Furthermore, for simplicity we will assume that the incumbent is located at 0 (the left end of the line) and the entrant is located at 1.

4.1 Results

We are now interested in seeing under which circumstances the incumbent (and the entrant) prefer a situation in which an authorized generic is present or not.

We find that if both firms have identical costs such that $c_B = c_G$, then the incumbent will always prefer not to introduce an authorized as $\Pi_2 > \Pi_3$. However, if production costs differ there are some situations in which $\Pi_2 < \Pi_3$ and thus the incumbent will want to launch an authorized generic. Additionally we can show that the incumbent will always obtain a lower profit if an authorized generic was licensed out rather than offered directly by the incumbent himself.

Consider first the situation where only a branded and generic good is offered. Among the consumers, there will be an indifferent consumer located at b_0 for whom at the given prices p_B, p_G the utility from either product is the same:

$$a - p_B - b_0^2 = a - p_G - (b_0 - 1)^2,$$

which can be solved for b_0 such that $b_0 = \frac{p_G - p_B + 1}{2}$.

Since all consumer to the left of b_0 will prefer the brand product b_0 signifies the demand for the brand product and $1 - b_0$ represents the demand for the generic. We can now express the incumbent's profit function as:

$$\Pi_2 = b_0 (p_B - c_B)$$

Similarly, the entrant's profit is given by:

$$\pi_2 = (1 - b_0) (p_G - c_G)$$

By taking derivatives w.r.t. their respective prices and setting them equal to zero, we obtain their respective best-response function,

$$p_B = \frac{1 + p_G + c_B}{2} \text{ and } p_G = \frac{1 + p_B + c_G}{2},$$

which can be solved for the equilibrium prices and profits: $p_B = \frac{3+2c_B+c_G}{3}$ and $p_G = \frac{3+2c_G+c_B}{3}$ and $\Pi_2 = \frac{(3-c_B+c_G)^2}{18}$ and $\pi_2 = \frac{(3+c_B-c_G)^2}{18}$

We can follow similar steps to determine the equilibrium prices and profits when the incumbent in addition to the brand product also offers an authorized generic. Assume in the context of the model that the "location" of the authorized generic is exogenously given as $z \in (0, 1)$. The implicit assumption here is that the authorized generic is more similar to the brand product and the generic than the brand product is to the generic, and that the incumbent has no control over the extent to which the authorized generic is differentiated from both the brand product or the generic.

In this setting, we have two indifferent consumers: One located at b_1 , who is indifferent between the brand product and the authorized generic, and another indifferent consumer located at $b_2 > b_1$, who is indifferent between the authorized generic and the generic.

Using the same type of indifference condition as before, $U(p_B, b_1, 0) = U(p_{AG}, b_1, z)$ and $U(p_{AG}, b_2, z) = U(p_G, b_2, 1)$ we can solve for the respective demands for the three different products: The demand for the brand product, generic and the authorized generic are

$$b_1 = \frac{z^2 - p_B + p_{AG} - z^2}{2z}, b_2 = \frac{p_G - p_{AG} + 1 - z^2}{2(1 - z)} \text{ and } b_2 - b_1$$

respectively.

The incumbent's profit is now given by $\Pi_3 = b_1(p_B - c_B) + (b_2 - b_1)(p_{AG} - c_{AG})$ and the entrant's profit is $\pi_3 = (1 - b_2)(p_G - c_G)$

We can solve for the equilibrium prices and profits in the same way as before and find:

$$p_B = \frac{4c_B + 2c_G + 6 - 4z + z^2}{6}, \quad p_{AG} = \frac{2c_B + c_G + 3 - 2z - z^2}{3} \quad \text{and} \quad p_G = \frac{c_B + 2c_G + 3 - 4z + z^2}{3},$$

as well as

$$\begin{aligned} \Pi_3 &= \frac{z(6 - 2c_B + 2c_G - 4z + z^2)}{24} + \frac{[2c_G - 2c_B + (1 - z)(6 - z)](3 - c_B + c_G - 2z - z^2)}{36(1 - z)} \quad \text{and} \\ \pi_3 &= \frac{(3 + c_B - c_G - 4z + z^2)^2}{(18 - 18z)} \end{aligned}$$

Comparing Π_2 and Π_3 , we find:

Proposition 9 *If both firms have identical per-unit costs, then the incumbent never prefers to launch an authorized generic*

If $c_B = c_G$, then $\Pi_2 > \Pi_3$ because $\Pi_2 = \Pi_3 + \frac{z(12+20z-5z^2)}{72}$ with $\frac{z(12+20z-5z^2)}{72} > 0$ for $z \in (0, 1)$.

Suppose instead $c_B < c_G$, such that $c_B = k c_G$ with $k < 1$. Let $\underline{c}_G = \frac{1-z}{k-1} + \frac{1}{2}\sqrt{\frac{(16-21z^2+5z^3)}{(k-1)^2}}$ and $\overline{c}_G = \frac{4z-z^2-3}{k-1}$ represent lower and upper bound for the per-unit cost of the entrant. Then $\Pi_2 < \Pi_3$ obtains under the following circumstances.

Proposition 10 *If $c_B < c_G$, $z < 0.5239$ and $c_G \in [\underline{c}_G, \overline{c}_G]$, then the incumbent prefers to launch an authorized generic and in equilibrium quantities for all three products are strictly positive.*

Roughly speaking the intuition here is that an incumbent benefits from offering a second product, the authorized generic, that is better positioned to reach "far-away" customers without having to reduce prices too much. Because

the incumbent has a production cost advantage, the losses that the incumbent suffers from the introduction of the authorized generic - in the form of some consumers switching from the more expensive brand product to the cheaper authorized generic - are more than offset by the gains the incumbent makes by taking away demand/market share from the entrant.

For example when $c_G = 1.35$, $z = 0.4$ combined with $k = 0.1$ will result in an equilibrium as described in the proposition above. Any larger value for z will lead to a corner solution for the indifferent consumers and thus imply that either the entrant or the incumbent will face zero demand on one of their products

Finally, if $c_B > c_G$ it is straightforward to show that it is always preferable for the incumbent not to launch an authorized generic, as whenever $k > 1$ there exists no value of $z \in (0, 1)$ such that $\underline{c}_G < \overline{c}_G$.

Comparing profits for the entrant, we find

Corollary 11 *For any c_B , c_G , the entrant prefers a market without authorized generics as $\pi_2 > \pi_3$.*

Hence, if $c_B = c_G$, the overall producer surplus falls with the introduction of the authorized generic such that $\Pi_3 + \pi_3 < \Pi_2 + \pi_2$.

4.2 A numerical example

We now revisit the policy question we posed earlier : Recall that the policy maker may be interested in encouraging the introduction of an authorized generic. Suppose that as before he can provide subsidies. Can he compel the incumbent to launch an authorized generic and prevent the entrant from accepting any settlement offer ? Also, in terms of consumer surplus is such an intervention by the policy maker desirable ?

We provide a numerical example in which the policy maker taxes the entrant and subsidizes the incumbent in order to provide an incentive for the incumbent to not seek a settlement and rather launch an authorized generic. We will further show that consumer surplus improves given such a change and that the gain in consumer surplus outweighs the net cost of subsidization.

For the consumers' utility function, suppose that $a = 2.334$. Further, for the incumbent's and entrant's production cost assume $c_B = 0.3$ and $c_G = 1.3$. Finally, assume that any authorized generic if introduced to the market will be located at $z = 0.4$:

If we calculate the firms' profits in markets with or without authorized generic we find:

$$\begin{aligned}\Pi_2 &= 0.8888, \Pi_3 = 0.8637 \\ \pi_2 &= 0.2222, \pi_3 = 0.029\end{aligned}$$

We see from the above numbers that $\Pi_2 > \Pi_3$ and thus the incumbent has no incentive launch an authorized generic if the entrant were to enter the market. Additionally, we see that $\Pi_3 + \pi_3 = 0.8927$ and $\Pi_2 + \pi_2 = 1.111$.

Given $a = 2.334$ and $c_B = 0.3$ we find that $\Pi_m = 1.1165$: We know as $\Pi_m > \Pi_2 + \pi_2$ the incumbent would then seek a settlement with the potential entrant, whereby he would offer him (in the single period model) a payment $x = \pi_2$ in exchange for the entrant staying out of the market. In such a scenario the incumbent monopolist will serve some consumers⁵, charge a (limit) price $p_m = \frac{1}{3}(2a + c_B) = 1.656$ and leave the consumers a surplus of

$$CS_m = \int_0^{z_0} (p_m - z^2 - c_B) dz = 0.3722.$$

⁵The monopolist maximizes $(p_m - c_B) x_0$, where $x_0 = \sqrt{a - p_m}$ represents the demand (and the fraction of consumers served).

Suppose now the policy maker intends to prevent such an outcome. In order to do so, he would have to make the settlement unattractive to the two firms and provide the incumbent with an incentive to launch an authorized generic. The policy maker may tax the entrant such that its production cost change to $c'_G = 1.75$ while he subsidizes the incumbent such that $c'_B = 0.2$.

Under such circumstances the firms' profits can be re-calculated as:

$$\begin{aligned}\Pi'_2 &= 1.1501, \Pi'_3 = 1.2013 \\ \pi'_2 &= 0.1168, \pi'_3 = 0.000001\end{aligned}$$

Given the changed production costs, see that $\Pi'_3 + \pi'_3 = 1.2013 > 1.2 = \Pi'_m$ - a settlement no longer is attractive as the two firms can obtain the same aggregate surplus under competition (which now includes subsidies). Additionally, we now have $\Pi'_3 > \Pi'_2$ making it profitable for the incumbent to launch an authorized generic which will lead to higher profits for him.

In equilibrium, the entrant will have a market share of 0.278%, with the remainder split between the brand product (10%) and the authorized generic (89.722%).

The net cost of subsidization will be

$$(c_B - c'_B)0.9977 - (c'_G - c_G)0.00278 = 0.09852.$$

This compares against the gain in consumer surplus by having three products (brand, generic & authorized generic on offer): Given $a = 2.334$, the consumer surplus in equilibrium under the given production costs will be $CS'_3 = 0.848$. Given that consumer surplus in monopoly is $CS_m = 0.3722$ as shown above, and under competition without an authorized generic it is $CS_2 = 0.4784$ we see

that under either scenario the gain in consumer surplus significantly outweighs the net cost of subsidization and therefore is welfare-enhancing.

Intuitively, the government rewards the incumbent to launch a second product that is primarily designed to serve consumers that the incumbent otherwise would have no interest in serving. Because the consumer benefit from consumption is large ($a = 2.334$), the cost of subsidization is small relative to the consumer gains thus leading to welfare improvements. The subsidies to the incumbent will have to be large enough such that the incumbent no longer has any interest in maintaining his original monopoly position by reaching a (reverse) settlement with the potential entrant.

5 Conclusion and Outlook

In this paper, we employed a simple model framework to provide some basic analysis of reverse settlements in pharmaceutical markets subject to the Hatch-Waxman Act. We examined how a number of policy options - subsidies/taxes, a ban on authorized generic, restrictions on the terms of a reverse settlement - would impact the market outcome and whether consumers would benefit from such policies.

We provided a numerical example for a situation in which subsidies lead to welfare improvements, which indicates that there is at least some scope for government intervention.

However, the simplicity of the model also results in a number of limitations: The model does not account for uncertainty about court decisions etc, which often is an aspect that firms involved in Paragraph IV ANDA cases have to consider. In a sense, our model implicitly assumes that the entrant is certain to win approval and certain to win any court decision. Also, our model does not consider the decisions that have to be made by the two firms in the time prior to the filing of an Paragraph IV ANDA - that is, we do not model the investment

and development decisions and whether or when to file for a Paragraph IV ANDA. In the discussion about authorized generics, this of course is important, because the (potential) threat of facing an authorized generic may very well impact the decision by a potential entrant to start development of a particular generic drug and/or the decision to file for approval. In our model, we are thus only conducting an analysis of the post-investment decision situation.

Finally, in our extended model and numerical example we assume - among other things- a uniform distribution of consumers, a constant per-unit marginal cost, as well as no fixed costs. This allows us to obtain closed-form solutions and calculate precise number results. However, this comes at the cost of making strong and restrictive assumptions. While our conjecture is that most results will follow through once we relax our functional form assumption, this will need to be verified.

In addition, given that at least in limited form there exist data on the various reverse settlements (see FTC (2002), FTC (2005) and Hemphill (2007) for summaries of data), an obvious next step would be to empirically address the issues raised in this paper, including testing some of the results of this paper.

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